

### **REMARKS**

This responds to the Office Action mailed on March 5, 2007.

No claims are amended, canceled, or added; as a result, claims 1, 4, 7-22, and 25 are now pending in this application.

#### **§102 Rejection of the Claims**

Claims 1, 4, 7, 13, 14, 20, 21 and 25 were rejected under 35 U.S.C. § 102(b) as being anticipated by US 6,060,085 to Osborne or US 5,863,560 to Osborne (as evidenced by Russell, AFP, 2000).

Osborne '085 is a continuation of Osborne '560. In order to simplify the arguments below, Applicant will refer only to Osborne, but the arguments apply to both Osborne '560 and Osborne '085. In addition, the Examiner appears to have mistakenly referred to the '085 patent as the '060 patent (beginning on page 3 of Office Action). Because there is no prior indication of any '060 patent and because the numbers before "085" in Osborne are "060," Applicant concludes that Examiner's '060 is meant to be the '085 Osborne patent. Applicant respectfully requests confirmation of this conclusion.

The Examiner has maintained the 35 U.S.C. § 102(b) rejection, concluding that both inflammatory and non-inflammatory lesions are inherent to the acne described in the teachings of Osborne and therefore the claimed method of reducing the number of non-inflammatory lesions and the treatment of non-inflammatory lesions of acne is inherent to the teachings of Osborne.

Applicant respectfully maintains the position that the Examiner's theory of inherency is misapplied. First, Applicant reiterates that the patent law on inherency relies on the fundamental, but not articulated, presumption of actual use. Because there was no actual use of Osborne's topical dapsone in treating conditions of any kind, Osborne does not inherently anticipate the use of dapsone in treating non-inflammatory acne. Second, Applicant argues that even if Osborne's topical dapsone had actually been used in treating inflammatory acne, the "normal and usual operation" of that treatment is the action of dabbing medication on the inflammatory papules and pustules, not smearing medication over the entire surface of the skin. Thus, regions of skin containing non-inflammatory acne would not be treated by the normal and

usual operation of treating inflammatory acne in Osborne. Finally, in the contexts of both actual use and “normal and usual operation,” Applicant reiterates that anticipation cannot attach because the treatment of non-inflammatory acne would not necessarily occur each and every time the prior art dapsone were used to treat inflammatory acne. Applicant will further elaborate on these arguments below.

### Actual Use

It remains Applicant’s position that the patent law on inherency generally relies on a fundamental, but not articulated, presumption of actual use. As discussed previously, the case law (including *In re May*, *In re Crish*, *In re Best*, and *In re Cruciferous Sprout Litigation*) supports this position. Although anticipation was upheld in these cases, Applicant points out that the compositions or methods claimed in each instance had actually been used. In contrast, Osborne’s topical dapsone was never actually used to treat any form of acne, nor any other ailment. The formulation was merely applied to the skin of cadavers to test its permeation and retention abilities; no conditions were treated by this application to the skin. It would thus be impossible for Osborne’s method of use of dapsone to inherently treat non-inflammatory acne, since until the instant application dapsone had never before been applied to living skin for use in treating any type of ailment.

Additionally, because an inherent feature must be present every time the prior art method or composition is used (see Donald S. Chisum, CHISUM ON PATENTS § 3.03[2][b], 2006), it would be impossible to conclude that Osborne’s topical dapsone could inherently treat non-inflammatory acne. The topical dapsone was never actually used in treatment; thus, it could not have treated non-inflammatory acne every time it was used. Applicant thus respectfully submits that inherent anticipation of the use of topical dapsone to treat non-inflammatory acne cannot be found without the real and necessary element of actual use in Osborne.

On page 6 of the most recent Office Action, the Examiner responds to Applicant’s actual use arguments by citing *Gould v. Quigg*, 822 F.2d 1074, 1078, 3 USPQ 2d 1302, 1304 (Fed. Cir. 1987) to support the position that Osborne’s method of treating inflammatory acne with dapsone anticipates the claimed new use of treating non-inflammatory acne. Specifically, the Examiner states that *Gould* supports the conclusion that actual use is not required when a reference teaches

the composition or method, and that inventions need not have actually been reduced to practice prior to filing. Applicant respectfully argues that the Examiner's conclusion is incorrect, and points out that *Gould* applies only to enablement situations under 35 U.S.C. § 112, not to inherent anticipation situations under 35 U.S.C. § 102. *Gould* is cited in MPEP 2164.02, which is directed to working examples under the Enablement requirement (MPEP 2164). In *Gould*, the rejection was directed to enablement, not anticipation. Applicant has already stated that the issue here is not one of enablement, but rather one of actual use in inherent anticipation. Applicant and Examiner agree that Osborne's disclosure of the dapsone compositions and the use of dapsone to treat inflammatory acne are enabled. However, these enablement arguments do not apply to the analysis of actual use in inherent anticipation.

Thus, because Osborne's dapsone had never before been applied to living skin for use in treating any type of ailment, inherent anticipation of the claimed methods cannot be found.

#### Normal and usual operation

To support her inherency argument, the Examiner also contends that a prior art device inherently performs a given function disclosed in the method claims when the device is used in "normal and usual operation." *In re King* (801 F.2d 1324, USPQ 136 (Fed. Cir. 1986)). The Examiner concludes that the Osborne teaching of the use of dapsone in "treating inflammatory acne" can be construed as "normal and usual operation," and thus dapsone also inherently performs the function of treating non-inflammatory acne. It is unclear to Applicant exactly how the Examiner reaches this conclusion, but Applicant believes that the Examiner could have reached this conclusion by two possible lines of reasoning.

One possibility is that the Examiner could be comparing the "normal and usual" actions carried out when treating inflammatory acne with the dapsone of Osborne to the normal and usual actions that would be carried out when treating non-inflammatory acne with dapsone. One could envision both of these actions as a similar topical application of dapsone to affected skin. The Examiner apparently thus concludes that dapsone inherently performs the function of treating non-inflammatory acne because one would go through the same motions in applying the dapsone topically for treating both types of acne.

However, Applicant argues that the normal and usual actions carried out when treating inflammatory acne are *different* from the actions carried out when treating non-inflammatory acne. In treating inflammatory acne, one does not smear the lotion or ointment all over one's face. Instead, one dabs the lotion or ointment onto the inflamed lesions only. Accordingly, when applying a dapsone formulation as described by Osborne, one would follow the physician's prescription and apply the formulation to those inflammatory papules and pustules in a spot-treatment fashion. This mode of treatment would not include regions of skin containing only black-heads. Consequently, it would be impossible for regions of skin containing non-inflammatory acne to be treated by Osborne's normal and usual operation for treating inflammatory acne.

Alternatively, the Examiner could be concluding that because the most common form of acne comprises both inflammatory and non-inflammatory lesions (as shown in Russell), the normal and usual operation of applying the dapsone to inflammatory acne would necessarily result in the dapsone also being applied to co-existing non-inflammatory acne lesions. Applicant respectfully disagrees with this conclusion because again, in treating inflammatory acne, one does not smear the lotion or ointment all over one's face. Instead, one dabs the lotion or ointment onto the inflamed regions only. Thus, regions of skin containing black-heads are not treated by Osborne's normal and usual operation of treating inflammatory acne.

Additionally, Applicant has previously argued, and reiterates here, that simply because both forms of acne are usually present, does not mean that they always exist together, and does not lead to the conclusion that a treatment which is successful in reducing one form of acne necessarily succeeds in reducing the other form. Russell merely describes the most common situation; nothing in Russell indicates that a topical antibiotic such as dapsone would reduce both inflammatory and non-inflammatory acne. Indeed, those of skill in the art know that antibiotics are counter-indicated for the treatment of non-inflammatory acne (see the 37 C.F.R. §1.132 declaration of Robert Lathrop). Thus, to one of skill in the art, the normal and usual operation of applying a topical antibiotic is to reduce inflammatory acne, not non-inflammatory acne. The unexpected and surprising discovery that the antibiotic dapsone is effective in treating non-inflammatory acne lesions is embodied by the claimed invention, and does not fall under Osborne's normal and usual operation for treating inflammatory acne.

Finally, Applicant stresses that anticipation attaches only if the alleged inherent feature necessarily occurs each and every time the prior art composition or method is used (Chisum, *supra*), and an anticipation rejection that is based on inherency must be supported by factual and technical grounds establishing that the inherent feature must flow as a necessary conclusion, not simply a possible conclusion, from the teaching of the cited art. *Ex parte Levy*, 17 U.S.P.Q.2d 1461, 1464 (Bd. Pat. App. & Int. 1990); *In re Oelrich*, 666 F.2d 578, 212 U.S.P.Q. 323, 326 (C.C.P.A. 1981). The normal and usual operation taught by Osborne is directed to treatment of inflammatory acne only. As discussed above, not only was the operation not actually performed in Osborne, but the normal and usual operation of treating inflammatory acne does not include the treatment of non-inflammatory acne. The action of dabbing medication on the inflammatory papules and pustules does not treat regions of skin containing non-inflammatory acne. Thus, the treatment of non-inflammatory acne would not necessarily occur each and every time the prior art dapsone were used to treat inflammatory acne, and inherent anticipation cannot attach.

Applicant thus respectfully requests withdrawal of this rejection.

### §103 Rejection of the Claims

Claims 8-12, 15-19 and 22 were rejected under 35 U.S.C. § 103(a) as being unpatentable over US 6,060,085 in view of Russell, as applied to claims 1, 4, 7, 13, 14, 20, 21 and 25 above, and further in view of US 6,200,964 to Singleton et al. OR over US 5,863,560 ('560) in view of Russell, as applied to claims 1, 4, 7, 13, 14, 20, 21 and 25 above, and further in view of Russell and US 6,200,964 to Singleton et al.

The Examiner has maintained this rejection despite Applicant's arguments that the inherency issue was improperly carried over from the 35 U.S.C. § 102(b) rejection. The inherency doctrine has no place in the determination of the obviousness of a new use of an old compound (*In re Shetty*, 195 USPQ 753 (C.C.P.A. 1977) and *In re Dillon*, 13 USPQ2d 1335, 1348 (Fed. Cir. 1989)), and Applicant remains steadfast in the position that the treatment of non-inflammatory acne is not inherent to Osborne. Thus, the rejection under 35 U.S.C. § 103(a) is improper.

The Examiner presents the new argument that the combination of references cited for the 35 U.S.C. § 103(a) rejection are not directed to the claimed method, but are instead directed to

the claimed forms of the composition (i.e., cream, lotion, spray, etc.). The Examiner thus concludes that it would have been obvious to prepare the dapsone compositions of Osborne in these topical forms with an expectation to achieve the desired treatment of both types of acne lesions. Applicant respectfully disagrees with this conclusion.

Applicant contends that this is an improper rejection, because the claims at issue are method claims, not composition claims. In the rejected claims, Applicant is not attempting to claim the compositions themselves, but rather is claiming the methods using the compositions. Each of the rejected claims depends from claim 1, which recites a method for reducing non-inflammatory acne lesions with dapsone. Dependent claims include all of the limitations of the claims from which they depend (see MPEP 608.01(n)); thus, the method of treatment cannot be ignored in these rejections under 35 U.S.C. § 103. Applicant reminds the Examiner that the patentability of a new use for an "old" or known composition is a statutory mandate that has been relied on by the C.C.P.A. and the Federal Circuit. "See 35 U.S.C. § 101 (2000), identifying as patentable 'any new and useful improvements' of a process, machine, manufacture, etc); *In re King*, 801 F.2d 1324, 1326 (Fed. Cir. 1986) (principles of inherency do not prohibit a process patent for a new use of an old structure)." *Perricone v. Medicis Pharmaceutical Corp.*, 432 F.3d 1368, 1378 (Fed. Cir. 2005).

The only explanation provided by the Examiner regarding how Osborne, Russell and Singleton form the basis of the § 103 rejection is that Russell and Singleton disclose different skin types, creams, lotions, and sprays, so it therefore would have been obvious to prepare dapsone in those formulations with an expectation to achieve the desired treatment of acne lesions (both types). The only way to reach this expectation of treating both types of acne lesions with dapsone is to implicitly carry the inherency conclusion over from the 35 U.S.C. § 102 analysis of Osborne. No other basis for the § 103 rejection of the claimed method of treating non-inflammatory acne is provided by the Examiner. As stated above, inherency is an improper basis for a 35 U.S.C. § 103 rejection.

As Applicant has previously shown, the only "expectation" a person of skill in the art would have regarding the treatment of non-inflammatory acne with dapsone is that it would not work. The references teach away from the claimed invention. Applicant again refers to the declaration of Robert Lathrop and the disclosure of Sykes in reiterating the well known fact that

anti-microbials are counter-indicated for the treatment of non-inflammatory acne. Thus, the expectation to achieve the treatment of both types of acne with the topical dapsone of Osborne must result from the Examiner's improper application of the inherency doctrine. Because the theory of inherency fails, Applicant respectfully requests withdrawal of the rejection under 35 U.S.C. § 103.

In summary, the Examiner has continued to rely on a theory of inherency for each of her arguments in rejecting the claims of the instant application. The entire case stands or falls on whether the dapsone of Osborne '085 and '560 inherently possesses the ability to reduce non-inflammatory acne. Applicant first submits that because the dapsone method of Osborne was never actually used to treat any kind of condition in a living being, this method cannot be said to inherently possess activity useful in the treatment of non-inflammatory acne. Second, the "normal and usual operation" of the treatment of inflammatory acne is the action of dabbing medication on the inflammatory papule and pustule lesions, not smearing medication over the entire surface of the skin. Thus, regions of skin containing non-inflammatory acne would not be treated by the normal and usual operation of treating inflammatory acne in Osborne. In the context of these arguments, Applicant contends that because the treatment of non-inflammatory acne would not necessarily occur each and every time the prior art dapsone were used to treat inflammatory acne, anticipation cannot attach. Consequently, Applicant respectfully requests withdrawal of the rejections under 35 U.S.C. § 102 and 35 U.S.C. § 103.

**CONCLUSION**

Applicant respectfully submits that the claims are in condition for allowance and notification to that effect is earnestly requested. The Examiner is invited to telephone Applicant's attorney (612) 371-2106 to facilitate prosecution of this application.

If necessary, please charge any additional fees or credit overpayment to Deposit Account No. 19-0743.

Respectfully submitted,

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**CERTIFICATE UNDER 37 CFR 1.8:** The undersigned hereby certifies that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail, in an envelope addressed to: Mail Stop AF, Commissioner of Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on this 7<sup>th</sup> day of May 2007.

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